

REMARKS/ARGUMENTS

The instant amendment responds to the Office Action dated November 18, 2009.

Applicants have studied the Office Action and have made amendments to claims 1, 39, and 66 to further define the present invention. It is submitted that the application is now in condition for allowance.

Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated June 30, 2008, the Examiner:

- I. (1-2) rejected claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 under 35 U.S.C. § 103(a) as being obvious over Meeker (U.S. Patent No. 2,108,206) in view of Heil, Jr. et al. (U.S. Patent No. 5,514,174) (hereinafter "Heil, Jr.") and further in view of Ley (U.S. Patent No. 5,514,076);
- II. (3) rejected claims 1, 5, 11, 15, 17, 19, 37, 39, 88, and 89 under 35 U.S.C. § 103(a) as being obvious over Wittkamp (U.S. Patent No. 4,142,530) in view of Ley (U.S. Patent No. 5,514,076);
- III. (4) rejected claims 39 and 60 under 35 U.S.C. § 103(a) as being obvious over Biggs et al. (U.S. Patent No. 6,599,311) in view of Heil, Jr. (U.S. Patent No. 5,514,174); and
- IV. (5) rejected claims 39-54, 58, 59, 61-65, and 86 under 35 U.S.C. § 103(a) as being obvious over Meeker (U.S. Patent No. 2,108,206) in view of Heil, Jr. (U.S. Patent No. 5,514,174) and Ley (U.S. Patent No. 5,514,076), and further in view of Green (U.S. Patent 5,928,137).

I. (1-2) Rejection under 35 U.S.C. § 103(a) Meeker in view of Heil, Jr. and Ley

As noted above, the Examiner rejected claims 1-10, 12-16, 18, 20-25, 27-36, 38, 55-57, 66, 83-85, and 87 under 35 U.S.C. § 103(a) as being obvious over Meeker (U.S. Patent No. 2,108,206) in view of Heil, Jr. (U.S. Patent No. 5,514,174) and further in view of Ley (U.S. Patent No. 5,514,076). Reconsideration of the application is requested.

As will be explained below, in light of the Examiner's statements in item 6, Response to Amendment, describing the reasons for rejection of the claims in the instant Office action, Applicants have amended claims 1 and 66 to further define the invention. Support for the claim amendments can be found in, for example, FIGs. 6 and 7 of the instant application and as described in the application as originally filed. No new matter has been added.

Specifically, claim 1 now recites, *inter alia*:

said head defining at least a portion of a set of curved tracks, each track having a respective arcuate segment **having concentrically-curved opposing sides**.

Claim 66 now recites, *inter alia*:

said head defining two opposing openings and at least a portion of a set of curved tracks, each track having a respective arcuate segment **having concentrically-curved opposing sides**.

As the Examiner states in item 6 on pages 8 and 9 of the instant Office action, the Examiner is interpreting what Heil Jr. itself refers to as an "opening 139" as, not just an opening, but as a "track." The Examiner supports his conclusion by citing to the ENCARTA World English dictionary's definition of "track" as a "path: path or road," which the Examiner analogizes to the "opening 139" of Heil Jr. Instant Office action, page 9. The Examiner, however, stops short of providing the definitions of the terms "path" or "road," neither of which support a comparison of Heil Jr.'s "opening 139" to the track of the instant invention. Merriam-Websters Online dictionary (www.merriamwebster.com) defines "path" as "a trodden way; a track specially constructed for a particular use; a: course, route...; a: the continuous series of positions...b: a sequence of arcs in a network that can be traced continuously without retracing any arc and road"

and a “road” as “a route or way to an end”. Applicants submit that neither of these definitions describes the opening 139 of Heil Jr. or supports the Examiner’s position. Regardless, the claims of the instant application have been amended to clearly define the invention as shown in the drawings and described in the application as originally filed.

First, Meeker discloses an instrument including a retraction device for manipulating or grasping an object with teeth. As shown in Fig. 4 of Meeker, the outer surface of the barrel has openings where the teeth exit and enter. The specification describes these openings in the barrel as “slots” where the points or prongs of the teeth project from or are drawn into the barrel. See Meeker at col. 1 (right), lines 15-18.

As shown in FIGS. 7 and 8 in the instant invention, the curved track 521 defines a path in which the needles travel. The track is not merely an opening or “slot” where the teeth actuate, as in Meeker, but is a defined arcuate segment in which the needles travel. More specially, as is now recited in the amended claims as “having concentrically-curved opposing sides.” This feature is neither present in nor suggested by Meeker.

As Meeker clearly does not teach the curvature of the arcuate segments, the Examiner combines Meeker with Heil, Jr. to form a first combination of this three-reference obviousness rejection under Section 103(a). The combination of these two references does not assist the Section 103 rejection because neither the curved hook in Heil, Jr. nor the teeth of Meeker is slidably present within a “respective arcuate segment having concentrically-curved opposing sides” as recited in the amended claim language of the instant application. If neither reference discloses or suggests this claimed feature, the combination thereof cannot be said to suggest this feature. More particularly, FIG. 5 of Heil, Jr. (reproduced below for the Examiner’s convenience) conspicuously illustrates the opening 139.

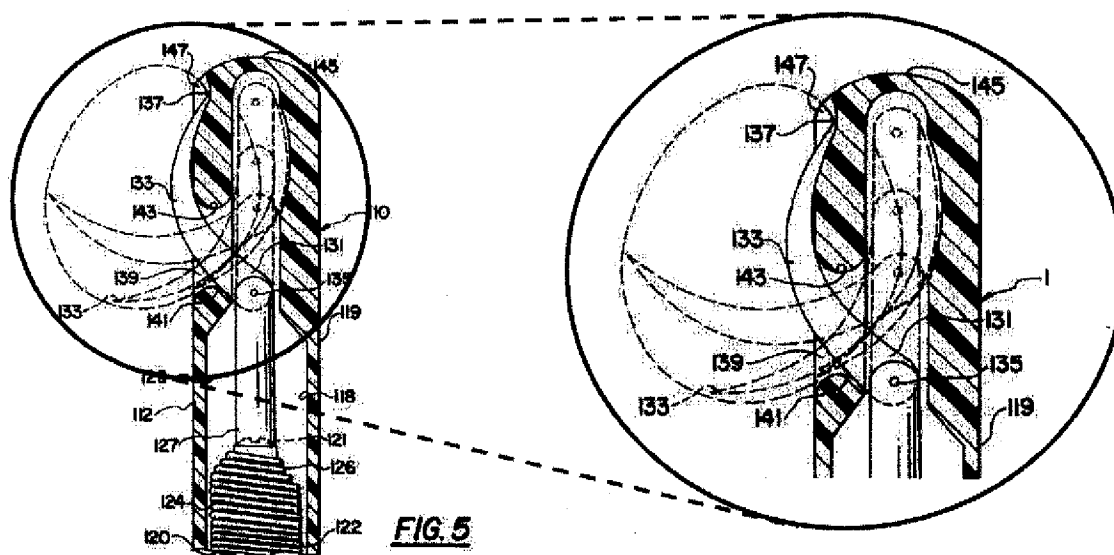


FIG. 5 of Heil, Jr.

The meaning of Heil, Jr.'s term "radial opening", when viewed in association of FIG. 5 of Heil Jr., becomes apparent. The opening of the tubular houses where the curved hook 133 resides and pivots on the thrust rod based on its actuation. The outermost edges of this opening have a radial shape and this shape provides a greater degree of travel for the curved hook 133, **but it is not a track as defined in the claims.** The Examiner, on page 9 of the instant Office action, compares the surfaces 141 and 143 of Heil Jr. to the curved tracks of the claimed invention. However, the surfaces 141 and 143 are curved in opposite directions, i.e., **away from each other.** Heil Jr. clearly does not teach, show, or suggest "a set of curved tracks, each track having a respective arcuate segment having concentrically-curved opposing sides," as recited in amended independent claims 1 and 66.

In stark comparison to Heil Jr., and as shown in FIG. 7 of the instant invention (presented below), the needles 4 are guided and supported by the track 521 while the needles 4 extend and retract through the head 52. See Specification at page 4, paragraph 0062. The track 521 is clearly shown in FIG. 7 as having two sides opposing one another at the needle 4, where the surfaces are arcuate and curve in the same direction and share a common axis, i.e., they are substantially concentric.

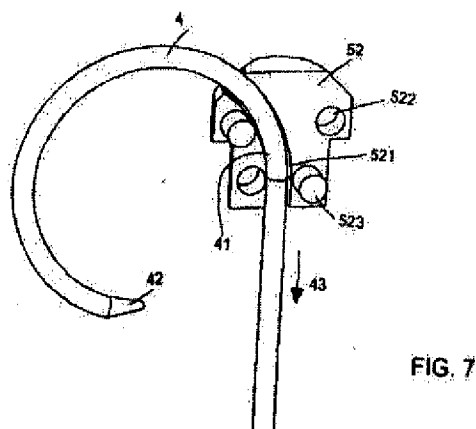


FIG. 7 of 10/728,389

Neither Meeker nor Heil, Jr. teach flexible needles that are of a shape-memory material having a memory shape. As such, the Examiner finished the tri-partite combination by adding Ley to the disclosures of Meeker and Heil, Jr. However, like Meeker and Heil, Jr., Ley also does not disclose or suggest “a set of curved tracks, each track having a respective arcuate segment having concentrically-curved opposing sides,” as set forth in amended claims 1 and 66. Ley merely discloses a surgical retractor used to pull away anatomical structures following an incision. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to combine Meeker in view of Heil, Jr. in further view of Ley to arrive at the instant invention. Moreover, when viewed in combination, none of the aforementioned references disclose **a set of curved tracks, each track having a respective arcuate segment having concentrically-curved opposing sides.**

The Supreme Court has held that the Federal Circuit’s teaching, suggestion, or motivation test is not inconsistent with the analysis set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and can be used in the “expansive and flexible approach” of determining obviousness *vel non*. *KSR*, 127 S. Ct. at 1739. See also *DyStar Textilfarben GmbH & Co. Deutschland KG. v C.H. Patrick Co.*, 464 F. 3d 1356, 1367 (Fed. Cir. 2006) (flexible approach); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (flexibility in obviousness

jurisprudence). Applied to the circumstances here, there is no teaching, no suggestion, and no motivation in the cited prior art to arrive at the features of the instant claims.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when “it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant”. *Interconnect Planning Corp. v. Feil*, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). “Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination”. *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). “Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so.” *ACS Hospital Systems, Inc. v. Montefiore Hospital et al.*, 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). “Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be ‘**clear and particular.**’” *Winner Int’l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants respectfully believe that there is no “clear and particular” teaching or suggestion in Meeker to incorporate the features of **both** Heil, Jr. **and** Ley, and there is no “clear and particular” teaching or suggestion in **both** Heil, Jr. **and** Ley to incorporate the features of Meeker.

In establishing a *prima facie* case of obviousness, **it is incumbent upon the Examiner** to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicant’s disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The Examiner has not provided the

requisite reason why one of ordinary skill in the art would have been led to modify Meeker with **both** Heil, Jr. **and** Ley or to combine Meeker's teachings with **both** Heil, Jr.'s **and** Ley's teachings to arrive at the claimed invention.

The Examiner simply has failed to meet the burden for satisfying the above requirements to allow a combination rejection to stand. Thus, it must be reversed.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs. Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1 and 66. Claims 1 and 66 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 1 or claim 66.

II. (3) Rejection under 35 U.S.C. § 103(a) Wittkampf in view of Ley

As noted above, the Examiner rejected claims 1, 5, 11, 15, 17, 19, 37, 39, 88, and 89 under 35 U.S.C. § 103(a) as being obvious over Wittkampf (U.S. Patent No. 4,142,530) in view of Ley (U.S. Patent No. 5,514,076). Reconsideration of the application is requested.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Independent claims 1 and 39 recite, *inter alia*:

flexible needles of a shape memory material having a memory shape-including a portion with an arcuate shape,
each of said needles being disposed slidably within a
respective one of said arcuate segments; and

an actuation device connected to said proximal end of said body and
operatively connected to said needles through said body, said
actuation device, upon actuation thereof, moving said needles to
selectively extend said needles out of said head through said arcuate
segments **in substantially opposite directions** and withdraw said
needles into said head through said arcuate segments.

Wittkampf discloses an epicardial lead with electrode tips 38-1, 38-2 adapted to secure the device to the epicardium and to deliver electrical signals. As shown in FIG. 1 of Wittkampf; the electrode contact elements 38-1, 38-2 are in a fixed position and are used to prevent movement of the electrode head in a *backwards* direction. See Wittkampf at col. 3, lines 23-53.

Wittkampf also discloses an anchor 40 which is “preferably constructed of nylon, or other suitable plastic” and “may also be of a suitable metal.” Wittkampf, col. 3, lines 53-66. According to Examiner, “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ley, to form needles in the device of Wittkampf out of a shape memory material having a memory shape.” Instant Office action, pages 5-6. The Examiner goes on to say that “[s]uch a material...would allow the needles to have remarkable shape recovery...” *Id.* page 6.

Contrary to the Examiner’s conclusion, however, Wittkampf teaches away from “flexible needles of a shape memory material having a memory shape including a portion with an arcuate

shape.” Prior art that *teaches away* is per se demonstration of lack of prima facie obviousness.¹ A reading of the full disclosure of Wittkampff reveals that the purpose of the anchor is to extend forward and secure the device in a direction *opposite* the direction in which the contact elements 38-1, 38-2 secure the electrode. Wittkampff states that “[t]he anchor, or forward barb, is preferably constructed of nylon, or other suitable plastic, of sufficient strength so as to provide a good mechanical hook for fixation into the heart.” *Id.* Therefore, Wittkampff is teaching that the anchor must be stiff and must extend in a direction *opposite* the reverse-pointing tips of the contact elements 38-1, 38-2. If the anchor 40 was bent, it would no longer extend in the direction *opposite* the reverse-pointing tips. Therefore, Wittkampff teaches providing the anchor 40 with *no* arc – i.e., it cannot have “a memory shape including **a portion with an arcuate shape**,” as recited in claims 1 and 39 of the instant application. A view of FIG. 2 shows the path of the anchor 40, which is slightly bent before extending out of the casing 30. If the anchor had an arcuate shape, it would place the tip of the anchor 40 *closer* to the tips of the contact elements 38-1, 38-2; this is *undesirable* as it relates to Wittkampff because the electrode needs to be secured as well as possible. Therefore, no one skilled in the art would ever want to make the anchor 40 have an arcuate shape. In addition, the entire reason for the using the shape-memory material is so that the material can be manipulated to a different shape and that it will return to its natural shape. Because the shape-memory needles of the present invention are intended to be bent or otherwise manipulated (compare FIGs. 27 and 28 of the instant application), Wittkampff’s call for a stiff material *teaches away* from using flexible shape-memory material. Looking at FIG. 2 of Wittkampff shows that the anchor 40 extends relatively straight out of the casing 30. ANY bending at all once the anchor 40 is extended would be undesirable. Thus, the Examiner’s attempted substitution of shape-memory metal is impermissible.

The Examiner goes on to say that the “relatively low, predictable” bending of the shape-memory material would actually be desirable because “any inadvertent excessive force applied by a user, while the needles are in the tissue, would cause the needles to release.” Instant Office action, page 6. By making this statement, the Examiner is *impermissibly ignoring Wittkampff’s own statements to the contrary* calling for an anchor that has “sufficient strength so as to provide a

¹ See *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (U.S. 2007).

good mechanical hook for fixation into the heart”. See Wittkampf, col. 3, line 62 through col. 4, line 1.

In establishing a *prima facie* case of obviousness, the requisite **motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art** and not from the applicant’s disclosure. See, for example, *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), *cert. den.*, 488 U.S. 825 (1988). The Supreme Court holds that “**when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.**” *KSR*, 127 S. Ct. at 1740. For at least these reasons, it would not have been obvious to one of skill in the art to combine Wittkampf with Ley and Ley cannot properly be combined with Wittkampf, as suggested by the Examiner.

Going further, Wittkampf discloses an anchor 40 that is attached to a piston 41. Wittkampf, col. 3, lines 53-66. A stylet 44 is used to push the piston forward and extend out of the casing 30. Wittkampf, col. 4, lines 4-16. Notably, the stylet 44 is not attached to the piston 41. A nylon wire 45 that is a separate element from the stylet 44 is used to pull the piston backwards. Wittkampf, col. 4, lines 4-16. Therefore, Wittkampf does not teach, show, or suggest “an actuation device ... operatively connected to said needles through said body, said actuation device, upon actuation thereof, moving said needles to selectively extend said needles out of said head through said arcuate segments and withdraw said needles into said head through said arcuate segments,” as recited in amended claim 1 of the instant application.

Ley also does not teach, show, or suggest “an actuation device ... operatively connected to said needles through said body, said actuation device, upon actuation thereof, moving said needles to selectively extend said needles out of said head through said arcuate segments and withdraw said needles into said head through said arcuate segments,” as recited in amended claim 1 of the instant application.

Additionally, Wittkamp is entirely directed to maintaining contact between its knitted Dacron mesh 52 and the heart. For this specific reason, the anchor 40 and contact elements 38-1, 38-2 are located on the bottom 35 of the device. In fact, Wittkamp cannot have any extensions from the upper surface of the device because the only way to remove the elements 38-1, 38-2 from tissue is to push the device forward and to lift up on the device. Therefore, Wittkamp teaches away from "said needles ... extend ... out of said head through said arcuate segments in substantially opposite directions," as recited in independent claims 1 and 39.

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). The Examiner has attempted to meet his burden with an impermissible hindsight view of the current state of the art, thus, the combination rejection must fail.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1 and 39. Claims 1 and 39 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 1 or 39.

III. (4) Rejection under 35 U.S.C. § 103(a) Biggs et al. in view of Heil, Jr.

As noted above, the Examiner rejected claims 39 and 60 under 35 U.S.C. § 103(a) as being obvious over Biggs et al. (U.S. Patent No. 6,599,311) in view of Heil, Jr. (U.S. Patent No. 5,514,174). Reconsideration of the application is requested.

As the Examiner properly recognizes on page 10 of the instant Office action, "Biggs does not disclose curved tracks for passage of needles." However, as stated above, in the section entitled "I. (1-2) Rejection under 35 U.S.C. § 103(a) Meeker in view of Heil, Jr. and Ley," Heil Jr. **also fails** to teach, show, or suggest "a set of curved tracks, each track having a respective arcuate

segment having concentrically-curved opposing sides,” as recited in amended claim 39 of the instant application. Those arguments are incorporated by reference herein in their entirety.

Clearly, Biggs taken in view of Heil, Jr. does not show a set of curved tracks with arcuate segments as recited in claim 39 of the instant application. Claim 39 is, therefore, believed to be patentable over the art. The claims dependent therefrom are believed to be patentable as well because they all are ultimately dependent on claim 39.

IV. (5) Rejection under 35 U.S.C. § 103(a) Meeker in view of Heil, Jr., Ley, and Green

As noted above, the Examiner rejected claims 39-54, 58, 59, 61-65, and 86 under 35 U.S.C. § 103(a) as being obvious over Meeker (U.S. Patent No. 2,108,206) in view of Heil, Jr. (U.S. Patent No. 5,514,174) and Ley (U.S. Patent No. 5,514,076), and further in view of Green (U.S. Patent 5,928,137). Reconsideration of the application is requested.

As set forth above in the section entitled “I. (1-2) Rejection under 35 U.S.C. § 103(a) Meeker in view of Heil, Jr. and Ley,” Meeker in view of Heil, Jr., and further in view of Ley cannot be said to suggest the invention set forth in claims 1 and 66. Because the relevant features of claims 1 and 66 are also present in claim 39, the aforementioned arguments lay the foundation supporting why the combination of Meeker in view of Heil, Jr. and further in view of Ley does not disclose needles traveling through “curved tracks, each track having a respective arcuate segment having concentrically-curved opposing sides.” These arguments are hereby incorporated herein by reference. Although Green discloses a flexible endoscope, it does not overcome the deficiencies of Meeker, Heil, Jr., and Ley to suggest claim 39. As such, this **four**-reference combination rejection fails.

As an aside, and as in the previous Office action, the Examiner rejects claim 39 as being unpatentable over Meeker in view of Heil, Jr. and Ley, and further in view of Green, yet **the Examiner fails to indicate why** Heil, Jr. was included in this Section 103(a) combination rejection. By failing to express **any** reasoning why Heil, Jr. was included in this four-reference combination rejection under Section 103(a), the Examiner acted contrary to *KSR*. Regardless of

the propriety of Heil, Jr.'s inclusion, the combination of the cited references, with or without Heil, Jr., do not suggest the features of claim 39.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claim 39. Claim 39 is, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claim 39.

CONCLUSION

The remaining cited references have been reviewed and are not believed to affect the patentability of the claims as amended.

In this Response, Applicants have amended certain claims. In light of the Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record. The foreseeable equivalents of any territory surrendered by amendment are limited to the territory taught by the information of record. No other territory afforded by the doctrine of equivalents is knowingly surrendered and everything else is unforeseeable at the time of this amendment by the Applicants and their attorneys.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

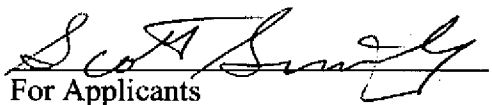
It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

If an extension of time for this paper is required, petition for extension is herewith made.

Please charge any fees that might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Mayback & Hoffman, P.A., No. 503,836.

PLEASE CALL the undersigned if discussion would expedite the prosecution of this application or in the event the Examiner should still find any of the claims to be unpatentable, in which case, if possible, patentable language can be worked out.

Respectfully submitted,


For Applicants

Scott D. Smiley
Reg. No. 55,627

SDS:gp

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**Mayback
& Hoffman, P.A.**

5722 S. Flamingo Rd. #232

Ft. Lauderdale, FL 33330

Office: 954.704.1599

Fax: 954.704.1588

Scott@Mayback.com

www.Mayback.com